DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 7 2001

Ms. Elise Johnston
MOLDED PRODUCTS, Inc.
601 Durant Street
HARLAN IA 51537

Re: K010712
Trade/Device Name: Re-Use/Washout Lines with connectors/adapters (Models #MPC-660, -640, -720, -710, -620, -715, -650, and -705)
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FID
Dated: June 26, 2001
Received: June 29, 2001

Dear Ms. Johnston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Molded Products
510(k): K010712 Re-Use WashOut Lines with Connectors

Description/Indications For Use:

The 8 rinse lines/connectors, which are the subject of this submission, are used during the cleaning, reprocessing, and disinfecting of a dialyzer. The lines are connected to the dialyzer and then to the rinse machine (Seratronics®/Fresenius' DPS-4, DRS-4, or Minntech's Renatron®) which primes the dialyzer with rinse solution and fills it with sterilant solution.

The MPC-660 rinse line is used to connect one blood port of a dialyzer to the opposite blood port creating a loop on the dialyzer while being primed with sterilant solution. The MPC-660 line may also be used for taking a sample of the sterilant solution during storage. This is done by inserting a needle through the access site on the MPC-660 line, and drawing a sample for testing.

The MPC-620, MPC-640, MPC-715, and MPC-720 are Y connectors that are used during the rinse procedure of a dialyzer. They connect each end of the two blood ports on a dialyzer to the (Seratronics®) reprocessing machine and allow cleaning solutions to flow from the machine to the dialyzer.

The MPC-650 and MPC-710 are single line connectors that are used during the rinse procedure of a dialyzer. They connect the blood port of the dialyzer to the (Renatron®) reprocessing machine and allow cleaning solutions to flow from the machine to the dialyzer.

The MPC-705 is a standard blood port to blood port Luer-Lock connector that is used with the MPC-715, MPC-710, and the MPC-720 lines. Use of the MPC-705 prevents cross-contamination of reprocessing lines to blood port of dialyzer.

All of the above devices are clean, but not sterile.

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010712

Prescription Use ✓ OR Over-The-Counter-Use _____